The Industrial Disease Standards Panel is a Schedule 1 Agency of the Government of Ontario attached to the Ministry of Labour. The function of the Panel, as defined in Section 86p of the Workers' Compensation Act of Ontario, is as follows:

(a) to investigate possible industrial diseases;

(b) to make findings as to whether a probable connection exists between a disease and an industrial process, trade or occupation in Ontario;

(c) to create, develop and revise criteria for the evaluation of claims respecting industrial diseases; and

(d) to advise on eligibility rules regarding compensation for claims respecting industrial diseases.

The Panel is required by statute to report its findings to the Workers' Compensation Board of Ontario.

Additional copies of this publication are available by writing:

Industrial Disease Standards Panel
10 King Street East, 7th Floor
Toronto, Ontario M5C IC3
(416) 965-5056

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REPORT TO THE WORKERS' COMPENSATION BOARD ON THE CGE LAMP PLANT ISSUE

Industrial Disease Standards Panel

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REPORT TO THE WORKERS' COMPENSATION BOARD

ON

THE CGE LAMP PLANT ISSUE

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Ontario
Ministry of
Labour

Ministère
du Travail
de l'Ontario

Industrial Disease
Standards Panel

Comité des normes
en matière de maladies
professionnelles

10 King Street East
7th Floor
Toronto, Ontario
M5C 1C3
416/965-5056

November 25, 1988

Dr. R.G. Elgie
Chairman
Workers' Compensation Board
2 Bloor Street East, 20th Floor
Toronto, Ontario
M4W 3C3

Dear Dr. Elgie:

In accordance with Section 86p(10) of the Workers' Compensation Act, I am pleased to convey herewith IDSP Report No. 5 which addresses the CGE Lamp Plant issue.

Yours sincerely,

J. Stefan Dupré
Chairman

JSD:jh

Ontario Ministry of Labour
Ministère du Travail de l'Ontario

Industrial Disease Standards Panel
Comité des normes en matière de maladies professionnelles

10 King Street East
7th Floor
Toronto, Ontario
M5C 1C3
416/965-5056

November 19, 1988

MEMORANDUM TO: **WORKERS' COMPENSATION BOARD**

FROM: **INDUSTRIAL DISEASE STANDARDS PANEL**

RE: **REPORT ON CGE LAMP PLANT ISSUE**

1.0 THE BOARD REFERENCE

1.1 In a letter dated June 24, 1987, the Board referred a reported excess of breast and gynaecological cancers among female workers in the Coiling and Wire Drawing (CWD) Department at the Toronto Dufferin St. plant of the Canadian General Electric Company to the Panel and requested advice on the following questions:

1. In the Panel's opinion, is there an occupational association between working in the Canadian General Electric Company (CGE) Dufferin Street Lamp Plant Coiling and Wire Drawing Department (CWD), and:

   (a) the development of breast cancer?
   (b) the development of gynaecological cancers?

2. If it is determined that there is an occupational association between working in the CGE CWD and the development of cancer:

   (a) What is the Panel's opinion regarding the likely causal agent or process? In particular, is there any evidence to suggest that exposure to methylene chloride may cause an increased incidence of breast cancer and/or gynaecological cancer in workers?

   (b) What should the standards of eligibility for compensation be? We considered the following criteria:
   - Duration and intensity of exposure;
   - Latency period from time of first exposure.

   (c) Under what circumstances would it be unlikely that there is an occupational cause? Should data be collected regarding such factors as:

- Familial history of breast or gynaecological cancer;
- Hormonal status;
- Age at first pregnancy;
- Age of onset of cancer.

(d) Should the compensation approach be founded on the Statutory Schedule, Policy Guideline or on a case by case adjudication basis?

1.2 The Board's letter of referral also mentioned that Mr. Elie Martel in November, 1982, had announced in the Legislature that 24 women in the CWD department of the CGE lamp plant had been diagnosed as having tumors, a number of which were malignant and at least 5 women had died of cancer at that point in time. As a result of these findings, an epidemiological investigation, led by Prof. Harry Shannon of McMaster University, was initiated in August, 1983, funded by the Board, the Ministry of Labour and the CGE Company. The Board's letter of referral is shown in its entirety in Appendix A.

1.3 The Board letter also contained the following attachments:

- An undated report of the results of the Shannon epidemiological investigation (entitled 'Cancer Morbidity in Lamp Manufacturing Workers');
- A Board-initiated review of the Shannon study by Dr. A.B. Miller (dated January 14, 1987);
- Two CGE-initiated reviews of the Shannon study by Drs. R. Monson and O. Wong (dated November 4-5, 1986);
- A review by Board staff (Dr. N.B. Hilliard) (dated November 27, 1986);
- The original Shannon study protocol (without appendices) dated April 18, 1983;
- Various journal articles, letters of correspondence and a NIOSH Current Intelligence Bulletin on methylene chloride.

2.0 PANEL INVESTIGATIONS

2.1 Panel staff met with parties of interest including labour and management representatives, and received information and materials from them related to this reference (United Electrical, Sept. 25, 1987). Staff also met with Dr. Richman (Heller, Dec. 2, 1987) and visited the CGE Oakville East plant (Heller, Sept. 9, 1988).

2.2 Professor Shannon provided panel with a complete copy of his study protocol including appendices dated April 18, 1983 (Shannon, June 9, 1988).

2.3 The Panel also received review papers on the risk factors associated with breast and endometrial cancers (Miller, Jan. 7, 1988); the toxicology of methylene chloride (Clary, June 6, 1988); and a critique of the methodology in the Shannon study (Andrews, Jan. 4, 1988). Professor Shannon provided responses to the critiques (Shannon, Nov. 4, 1987 and March 1, 1988) as well as additional study details (Shannon, September 20, 1988).

2.4 Panel also reviewed a variety of relevant literature and other information (see Appendix B for a complete listing of evidence).

3.0 THE ISSUES

3.1 The Panel has considered the several questions formulated by the Board in its reference of June 24, 1987. Having pondered these questions, the Panel has determined that they can be most appropriately addressed if they are approached as raising two distinct issues.

3.2 The first issue is the issue of probable connection. Is there a probable connection between breast and gynaecological cancers among CWD workers at the CGE plant and their workplace? Essentially, this issue encompasses the Board's questions 1.(a), 1.(b), and 2.(a).

3.3 The second issue is the issue of compensability. What are the considerations pursuant to which compensation might be awarded to the afflicted workers? This issue encompasses the Board's questions 2.(b), 2.(c), and 2.(d).

4.0 THE ISSUE OF PROBABLE CONNECTION

4.1 A brief chronology will help to place the information considered by the Panel in a clear and understandable order. In 1981, representatives of the union local of the Canadian General Electric lamp plant on Dufferin Street in Toronto reported a number of cases of female cancers among their fellow employees to the Joint Occupational Health and Safety Committee (JOHSC). Dr. Jack Richman, the occupational physician consultant to the CGE plant at the time, thereupon launched his own investigation by obtaining information on the health status of the CWD workers through personal interviews and medical insurance forms.

4.2 Dr. Richman's report was completed in June, 1982 and stated that "the purpose of this study was to investigate an apparently high incidence or prevalence of female tumors in the coiling area of the lamp department... despite the many

shortcomings of the investigative procedures, all methods of analysis seemed to show that there is a statistically significant increase in cancers of the breast, uterus, and cervix in the female population in the coiling area." Despite its methodological shortcomings, his study reported a total of 8 cancers among the CWD female workers (4 breast, 3 uterus and cervix, and 1 ovarian cancer) as well as 15 in the non-CWD areas of the plant. Richman's study became public knowledge when it was reported to the legislature on November 8, 1982 by Mr. Elie Martel.

4.3 Upon reviewing the Richman report, the JOHSC requested that McMaster University conduct an epidemiological study to determine whether or not there was a significant increase in breast and gynaecological cancers among the female workers in the CWD department in this plant. In November, 1986, Professor Harry Shannon of McMaster University presented the findings of his study to a public meeting of the workers. The study found a significant excess of breast and gynaecological cancers among the CWD female workers (specifically 8 breast, 1 cervix uteri, 2 body of uterus and 1 ovary for a total of 12 cases where 6.68 were expected).

4.4 In reflecting on the evidence before it, the Panel considers that the important threshold question is whether there is in fact a significant excess of breast and gynaecological cancers among the female CWD workers at the CGE Dufferin Street lamp plant.

4.5 In Table III of his study, Shannon reports that there is a statistically significant difference between the observed and expected number of breast and gynaecological cancers among the female CWD workers in this plant. As his test statistic, he uses the Standardized Morbidity Ratio (SMbR) for the combined site cancers, employing a two-sided test at the 5% level of significance. That is, his test answers the question: what is the probability that a difference in either direction as large (or larger) than the one between the observed and expected number of cancer cases at these combined sites could occur strictly due to chance alone? His answer is that the odds of this happening by chance are less than 1 in 20. Based on this test, one is compelled to conclude that it is more likely that the observed number of cases is <u>greater than the expected number</u>. He does not report any individual sites of cancer (either the breast, cervix uteri, body of uterus or ovary) as showing a statistically significant difference, again using a two-sided test at the 95% level. It should be noted that Shannon reports the 95% confidence limits on the SMbR of 180 for all gynaecological and breast cancers (in his Table III) as being 103 and 314 when they are in fact 93 and 314. This correction makes the reported SMbR not quite significant at the 5% level using a two-sided test.

4.6 In combining the cases of breast and gynaecological cancers (including the cervix uteri, body of uterus and ovary) before performing a statistical test of significance, Shannon made the assumption that this combining of sites was biologically plausible. Biological plausibility hinges on the argument that there is some evidence of a common, underlying biological model linking both the causal agent and the various cancer disease sites. The causal agent could be an identifiable putative workplace carcinogen (denoted for the moment as Substance X) about which there is either animal or human evidence linking Substance X exposures to the relevant cancers. Or the causal agent could be one or more human risk factors for which there exists either a body of animal or epidemiological evidence linking cancers at these sites to the risk factors (thereby implying a common underlying biological model, for instance, of the hormonal mechanisms in female biology).

4.7 In the matter of a putative workplace hazard ("Substance X"), methylene chloride was used as a degreasing solvent in the CWD environment at the CGE Dufferin St. plant during the relevant time period. In view of the National Institute for Occupational Safety and Health (NIOSH) Current Intelligence Bulletin No. 46 (April 18, 1986) recommending that methylene chloride be regarded as a "potential occupational carcinogen", Panel sought and received advice on its toxicology and particularly the significance of studies of animals exposed to methylene chloride (Clary, June 6, 1988). The animal data show that methylene chloride induces a significant excess of benign mammary tumours in rats (but not in mice or hamsters) at high exposure levels (500 ppm or greater) only. The Clary report stated that this benign tumour induction was species-specific (in rats only) and seemed to provide evidence of an indirect hormonal mechanism. There is some animal evidence, therefore, supporting the role of female hormonal mechanisms induced by methylene chloride in the production of benign mammary tumours.

4.8 As to the evidence from animal or epidemiological studies linking the cancer sites in question to common risk factors, the Panel received a report (Miller, Jan. 7, 1988) in which it was stated that:

> "in evaluating the possibility of a hazard, it would be far more rational to combine breast and endometrial cancer, than [to] combine either with cancer of the cervix uteri, or other gynaecological cancers as, with the exception of ovarian cancer, they have no risk factors in common. An example of a carcinogen effect is that of cigarette smoking. Smoking increases the risk of cancer of the cervix, but reduces the risk of endometrial

cancer, and probably has no effect on breast cancer (IARC Monograph on the Evaluation of the Carcinogenic Risk of Chemicals to Humans. Vol. 38, Tobacco Smoking, 1986)".

It appears, therefore, that an assumption of biological plausibility can reasonably sustain the linking of breast cancers with cancers of the body of the uterus and ovary, but not with cancer of the cervix uteri or other gynaecological sites.

4.9 In reanalyzing the data in Table III of Shannon's study by combining the cancer sites noted above, there results a total of 11 observed cases where approximately 5.54 would be expected, a finding which yields an SMbR of 199 which is of borderline statistical significance using a two-sided test at the 5% level (95% confidence limits: 99, 355).

4.10 It is worth noting that there is nothing sacred about the use of the 5% significance level. One could readily employ a 10% test of significance in which case the risk of being wrong (that is, of accepting a finding as significant when it is in fact due to chance alone) at this level would be less than 1 in 10 (or less than 10%). By this standard, both the findings of excess breast cancer alone and of excess combined cancers of the breast, ovary and body of the uterus are found to be significant.

4.11 However, Shannon notes in his protocol of April 18, 1983 (Appendix VI, Statistical Analysis of Data, p.31) that "tests will be one-sided, with the primary level of significance at alpha = 0.05". In a one-sided test, one asks whether or not the observed cases are <u>greater than expected</u>, statistically speaking. This is a less stringent test than the two-sided test reported in Table III. Using the one-sided test, the Panel has calculated that the individual breast site shows a significant excess of cancers at the 5% level as do the combined sites of breast, ovary and body of the uterus. To put it differently, the odds are less than 1 in 20 that one would observe this number of cases (or more) strictly by chance alone given the expected number of cases.

4.12 On the face of it, therefore, the study shows a near-significant excess of the combined cancers of the breast, body of uterus and ovary using a two-sided test at the 5% level. Alternatively, using a one-sided test at the 5% level, the Panel notes that there is a significant excess of breast cancer alone and of combined cancers at the sites noted above.

4.13 At this juncture, a critical issue of science needs to be addressed. This is whether the Shannon study validates or merely raises the hypothesis of industrial disease among the CWD female workers at the CGE Dufferin Street plant.

Management and both of the unions representing the workers have made extended attempts without success to find another lamp manufacturing plant in either Canada or the United States which would have lamp CWD production processes and technologies similar to those in the Dufferin St. plant. Should such a comparable plant have been found, then it would have been possible to determine whether or not the finding of these excess cancers could be verified among the Dufferin St. CWD female workers by studying the health experience of workers in the second plant. Lacking a comparable plant through which to validate the Dufferin St. findings, the Panel is faced with a single instance study reporting a significant excess of certain female cancers in a single workplace. Such studies are referred to as identifying 'clusters' of excess disease and epidemiologists generally consider that cluster studies raise hypotheses of excess disease but do not prove them.

4.14 In his study, Shannon states that anecdotal reports by CWD workers had raised the issue of excess "tumours of the breast and female reproductive system" among the workers in the CWD department, but that there was only one cancer (of the breast) thereby revealed. In the same study, he makes no mention of the Richman study (Richman, Drafts One and Two, 1982) which preceded it and which revealed a total of 8 cancers among the CWD female workers (4 breast, 3 uterus and cervix, and 1 ovarian cancer) as well as 15 in the non-CWD areas of the plant. However, Shannon's protocol, completed in April, 1983, states that "preliminary estimates found 8 malignant tumours at the sites noted above [breast cancer and female reproductive system]" (Protocol, p.2). This indicates that he must have been aware of these cases.

4.15 Epidemiologists call the cases to which the Shannon protocol refers 'index cases' because they are instrumental in the formulation of the hypothesis of excess disease. Various methods are suggested for dealing with cluster studies including the removal of index cases before undertaking the analysis, or the application of more stringent tests of significance. But all such methods are considered unsatisfactory because they involve ex post facto manipulations of the same data used both to raise and to verify the same hypothesis. Shannon notes in this regard:

> "All but one of the tumours that prompted the study were benign. Thus the cases found in this study are largely independent of the original cluster. We have thus used new data to test a previously generated hypothesis. (We might have omitted the a priori case but this would have created a bias since there is no definitive method to adjust the expected numbers. It should be noted that even if we had reduced the observed number of a priori

> cases by one and made no adjustment to the expected number the increase would still have been statistically significant)." (p.13)

Thus, Shannon is aware of the method of removing index cases before undertaking the analysis; but he refers to only one a priori case whereas there were in fact eight such cases. Removal of all eight cases before his analysis would have left the findings without interest.

4.16 The methodological critique of Shannon's study by Andrews (Jan. 4, 1988) mentions two central problems, that of multiple hypothesis testing, and that of selection effects. The first point relates to the number of hypotheses tested and the lack of appropriate levels of significance in their testing; the second refers to the selection effects preceding and precipitating his study. These include both the anecdotal worker reports and the Richman report. Andrews concluded, therefore, that:

> "Taking account of [the] multiplicity of possible tests and the selection effect- the effective level is much less significant than as stated. The stated level is so marginal that accounting for these effects would render it uninteresting.
>
> "There is no strong evidence to lead to the conclusion that the workplace is associated with risk."
> (Andrews, p.10)

In his response (Shannon, March 1, 1988) to the Andrews' critique, Shannon suggests that the methodological shortcomings in the Richman report were reason enough to ignore the reporting of the 8 cases of breast and gynaecological cancers in his own study.

4.17 It appears to Panel that, once Richman had reported 8 cases of breast and gynaecological cancer among the female workers of the CWD department, those cases were no longer a priori cases but rather were 'index cases'; and that mention of them should have been made in Shannon's study. The existence of these 8 index cases weakens the finding of significance of excess disease among these workers.

4.18 Based on the data in Tables V and VI of the study, the arrangement of the cancers of the breast, ovary and body of the uterus for the CWD female workers does support the argument that there may be a biological gradient of increasing risk with increasing 'exposure' (defined as years of employment in CWD). The Panel notes that the SMbR for the combined cancers among those workers with the longest exposure and the longest time since first exposure is significant at

the 5% level using a two-sided test. However, there are not enough data to develop a dose/response relationship fully. Nevertheless, the Panel observes that Table V for the combined sites noted above supports the possible existence of such a relationship.

4.19 Concerning the use of methylene chloride in the CWD environment from 1959 to 1985, the animal evidence shows that high exposures (of 500 ppm or more) lead to the production in rats (but not in mice or hamsters) of a significant excess of benign, but not malignant, mammary tumours (Clary, June 6, 1988). To date, human studies involving exposure to methylene chloride have failed to reveal any excess cancers. It therefore appears to Panel that the premise that methylene chloride may have played a role as a workplace carcinogen is unsubstantiated.

4.20 The Panel discovered that thorium oxide was used in the CGE Dufferin Street plant (Martin, June 13, 1988) but that its handling in a loose form was confined to another area of the plant (in another building and three stories away). Moreover, the epidemiological literature does not associate its use with any of the reported cancers. Trichloroethylene was employed as a degreasing solvent from the early 1950's to 1971 but the annual volumes used are unknown. As a result, the Panel cannot point to a causal agent which could have been the putative workplace carcinogen.

4.21 The Panel notes that breast cancer is the most common female cancer and the lifetime risk of a woman contracting this disease is about 10%. The reported excess number of cancers in the sites of interest are just over five; and of these five, four are breast cancers (Table III). In the population of some 204 CWD female workers, one would expect a normal occurrence of about 20 cases of breast cancer over the lifetime of the entire group.

4.22 To pursue this point, the Panel had analyses prepared on its behalf (Miller, July 15, 1988) by the staff of the Epidemiology Unit of the National Cancer Institute at the University of Toronto based on repeated random samplings from a cohort of women participating in the National Breast Screening Study (NBSS). Figure 1 shows the distribution of Standardized Mortality Ratios (SMRs) in 100 random samples from this cohort. This analysis illustrates how an SMR of 1.99 or greater (using the Panel's estimate of the combined site SMbR calculated in Paragraph 4.9 above) could arise by chance alone in 5 out of 100 samples drawn at random from a population with no increased risk for breast cancer. Figure 2 shows the distribution of observed to expected cases when 1,000 samples of size 100 each are drawn from the same cohort. Given a ratio of observed to expected cases of 1.99,

the graph shows that such a ratio could be exceeded by chance alone in 47 out of 1,000 samples or 4.7% of the time. Both figures clearly show how a finding of apparent statistical significance can arise by chance alone in a study group in which, by definition, there is no excess risk of breast cancer.

4.23 These facts suggest that the occurrence of a cluster of excess breast and gynaecological cancers could take place by chance alone. Indeed, it has been suggested that there could be any of a number of workplaces in Toronto and its vicinity employing female workers for which an appropriate epidemiological cohort study would reveal an excess number of breast cancer cases. This possibility weakens the hypothesis that the reported cancer cluster is workplace-related.

4.24 Is there other evidence that could serve to validate the hypothesis of the workplace-relatedness of this reported cancer cluster? Other comparable plants are seemingly not available. However, the separate evaluation of the health experience of this cohort of female workers for a period of time following 1982 (the end of the study followup period) would yield an independent estimate of the risk of breast and gynaecological cancers. Professor Shannon has provided the age distribution of the living members of this female cohort at the end of 1982 (Shannon, Sept. 20, 1988); and the Panel estimates that an additional followup of 5 years (from 1983-87) would produce fewer than 2 expected cases of female cancers at the sites in question (namely, breast, ovary and body of the uterus). A ten year followup (from 1983-92) would produce about 4 expected cases. In order to verify conclusively the existence of a probable connection between these diseases and the CWD workplace, the Panel could draw upon the protocol for the Shannon study (including a one-sided test of significance of 95%, the power of the study being greater than 80%, and assuming an SMbR of 200) and the data in his revised Table V showing excess cancers, namely the cells showing at least 15 years time since first exposure in CWD, to ask the following question. During the post-1982 followup period, what is the probability of observing excess cancers at these sites among the female CWD workers remaining in the Shannon cohort who have had at least 15 years elapse since their first exposure (to the CWD workplace)? A conclusive answer to this question by study of the surviving members of the original cohort would not be available until after the year 2000.

4.25 The Panel recapitulates the conclusions to which it has arrived in this section of its Report:

1. There is sufficient animal and human evidence to provide biological plausibility for the combining of breast cancers with cancers of the body of the uterus and ovary, but not with cancer of the cervix or other gynaecological sites.

2. Using a two-sided probability test of significance, there is a finding of excess breast cancer alone and of excess combined cancers of the breast, ovary and body of the uterus at the 10% level. At the 5% level, the excess of these combined cancers is of borderline significance.

3. Using a one-sided probability test of significance, there is a finding of excess breast cancer alone and of excess combined cancers at the 5% level. That is, the chances of making these findings using a one-sided test when there are in fact no excess cancers are less than 1 in 20.

4. However, Shannon's study does not mention the 8 cases of cancer at these sites reported by Richman. Because of Richman's report, these 8 cases were no longer a priori cases and their existence weakens the finding of significance of excess disease among these workers.

5. The data in Shannon's study support the possible existence of a biological gradient of increasing risk with increasing dose (measured as duration of employment in the CWD department). Indeed, the Standardized Morbidity Ratio for the combined cancer sites of the breast, ovary and body of the uterus among workers with the longest exposure and the longest time since first exposure is significant at the 5% level.

6. There is little evidence to support the premise that methylene chloride was the workplace carcinogen. Nor could the Panel identify any other hazardous substance which could have played the role of a causal agent in the production of these cancers.

7. Breast cancer is the most common female cancer and the lifetime risk of a woman contracting this disease is about 10%. For this reason alone, the cluster of excess breast and gynaecological cancers could have occurred by chance.

4.26 For these reasons, Panel Members Buck, Dupré, Gibson, LeVay, Miller and Stevens make the following finding:

FINDING 1: **AT THIS TIME, WE CANNOT MAKE A FINDING OF PROBABLE CONNECTION BETWEEN BREAST AND GYNAECOLOGICAL CANCERS AMONG CWD WORKERS AT THE CGE DUFFERIN ST. PLANT AND THEIR WORKPLACE. HOWEVER, THE EVIDENCE BEFORE US DOES NOT PRECLUDE THE POSSIBILITY OF WORK-RELATEDNESS. RESOLVING THE ISSUE BY EPIDEMIOLOGICAL MEANS REQUIRES A STUDY WHICH, AT THE EARLIEST, IS UNLIKELY TO YIELD AN ANSWER BEFORE THE NEXT CENTURY.**

4.27a In addition to the conclusions drawn above, Panel Members Gagnon and Jolley add the following:

1. In Paragraph 4.9, the Panel reanalysed the data in Table III of the Shannon study, using a Poisson distribution to yield an SMbR of 199, which is of borderline significance using a two-sided test at the 5% level, with the lower confidence level of 99. However, Shannon uses a Poisson distribution for expected numbers less than five and a normal distribution for expected numbers 5 or above. Using Shannon's methodology, the increase in cancer of the breast, body of the uterus and ovary reaches statistical significance on a two-sided test at the 5% level. But drawing a significant distinction between lower confidence levels of 99 or just above 100 suggests a precision that is not provided in epidemiology. And as stated in Paragraph 4.10, there is nothing sacred about the use of the 5% significance level.

2. In addressing the issue of whether this is a cluster or not, the report of Schulte et al. (1987) described 61 clusters in which the index cases were retained in all of the analysis, and therefore the test of significance and the criteria for duration of exposure and appropriate latent period were applied to further reduce the play of chance. The Shannon study meets both of these tests and should not require the removal of the index cases.

Using Shannon's analytical methods, the increase in cancer of the breast, body of the uterus and ovary is statistically significant in both the two and one-sided tests at the 5% level and Table V confirms a biological gradient of increasing dose, with a statistically significant increase in cancer of the breast, body of the uterus and ovary among the women with the longest duration and the longest latency, which according to the Schulte study would mean the possibility of a cluster in the CGE CWD area being chance-related represents a relatively rare event.

3. While no causative agent has been positively identified there are at least two potential carcinogens, methylene chloride and trichloroethylene, which have been identified by the National Institute for Occupational Safety and Health based on findings from the National Toxicology Program in the U.S.

The list of toxic substances in Table II of the study is clearly incomplete since trichloroethylene was not listed, and the fact that records are kept for only five years provides no assurance that the list is complete for the time period under study. And there is no exposure data for the substances of interest. However, probable connection has been made in other circumstances where potential carcinogens are present but the actual causative agent is unknown.

4. While the scientific evidence is not perfect, there are two problems that preclude the Panel from testing the hypothesis further. There is no other comparable facility and since the women workers in the CWD area were told that the increases in these cancers and especially breast were significant and breast screening or mammography was recommended, future follow up of this cohort may well be biased.

5. The Shannon study was funded by the company, Canadian General Electric, the Ontario Workers' Compensation Board, and the Ontario Ministry of Labour. The protocol for the study including the selection of the study population and the analytical methods were approved first by the company, CGE and the union representing the workers in that plant, the United Electrical, Radio, and Machine Workers of Canada, and then reviewed by both the WCB and the Ministry of Labour before agreeing to assist in the funding.

Therefore, it was the responsibility of all of these parties to ensure that the study be carried out in a manner consistent with proper epidemiological principles. The workers were certainly led to believe that all parties had agreed that the study constituted a proper scientific endeavour, and were told that the study did show a statistically significant increase in breast and gynaecological cancers and would form the basis for compensation.

4.27b For these reasons, Panel Members Gagnon and Jolley make the following finding:

FINDING 1A: AT THIS TIME, WE FIND A PROBABLE CONNECTION BETWEEN CANCER OF THE BREAST, BODY OF THE UTERUS AND OVARY AND WORK IN THE COIL AND WIRE

DRAWING AREA OF THE CGE DUFFERIN ST. LAMP PLANT.

4.28a Panel Member Chong follows an approach presented by Frumkin (1987) in arriving at his finding:

Step 1: Is a cancer cluster suspected? Answer: Yes.
Step 2: Is there really an excess of cancer? Answer: Yes.
Step 3: Is any particular type of cancer overrepresented? Answer: Yes (combining cancers of the breast, ovary and body of the uterus).
Step 4: Has sufficient latency elapsed? Answer: Yes (in 7 of the cases).
Step 5: Are any confounders likely to have contributed? Answer: No.
Step 6: Is any particular job type overrepresented among the cancer cases? Answer: Yes (working in the CWD workplace).
Step 7: Can any carcinogenic job exposures be identified? Answer: Possibly methylene chloride.
Step 8: Can any carcinogenic environmental exposures be identified? Answer: No (no data available).

Absence of an identified exposure to a putative workplace carcinogen weakens the occupational causation of the observed disease excess. The absence of this exposure information does not preclude the existence of a probable connection.

4.28b In line with these considerations, Panel Member Chong makes the following finding:

FINDING 1B: AT THIS TIME, I FIND THE EVIDENCE BETWEEN BREAST AND GYNAECOLOGICAL CANCERS AMONG CWD WORKERS AT THE CGE DUFFERIN ST. PLANT AND THEIR WORKPLACE APPROXIMATELY BALANCED FOR AND AGAINST WORK-RELATEDNESS. RESOLVING THE ISSUE OF PROBABLE CONNECTION BY EPIDEMIOLOGICAL MEANS REQUIRES A STUDY WHICH, AT THE EARLIEST, IS UNLIKELY TO YIELD AN ANSWER BEFORE THE NEXT CENTURY.

5.0 THE ISSUE OF COMPENSABILITY

5.1 There is nothing in the Workers' Compensation Act which requires, in the disposition of an individual claim, that a probable connection be established between a disease and a workplace as a condition of compensation. To the contrary, Section 3(4) of the Act stipulates:

> "In determining any claim under this Act, the decision shall be made in accordance with the real merits and

justice of the case and where it is not practicable to determine an issue because the evidence for or against the issue is approximately equal in weight, the issue shall be resolved in favour of the claimant."

5.2 One of the questions posed by the Board in the present reference asks whether its compensation approach should be founded on the statutory schedule, policy guidelines or case by case adjudication basis. As a general proposition, the Panel considers that statutory schedules or policy guidelines (eligibility rules) serve the important purpose of structuring the Board's discretion by providing criteria that are generally applicable to situations in which stipulated diseases are linked to corresponding workplaces. Being applicable to comparable situations as they arise, the criteria serve the goals of equity and predictability in compensation. So as to be credible to all concerned, such generally applicable criteria should rest upon scientific findings that establish a probable connection between diseases and workplaces.

5.3 But probable connection is not the determining issue in case by case adjudication. A plain reading of Section 3(4) makes it apparent that any claim under the Act calls for a Board decision made in accordance with the real merits and justice of the case. Section 3(4) further stipulates that where evidence for or against an issue is approximately equal in weight, the issue shall be resolved in favour of the claimant.

5.4 With respect to the merits and justice of compensation claims arising from the unique situation encompassed by the present reference, the Panel observes that it will not be possible to resolve the issue of probable connection by epidemiological means until the next century. This is in a context where the affected group of workers has lived under a cloud of doubt concerning its occupational health and safety since at least November of 1982. The Panel considers that to defer the issue of compensability for such a long time would be to transgress the rudimentary principle that justice delayed is justice denied.

5.5 As for weighing the evidence with respect to any particular claim, the issue is that of balancing the possibility of chance against the possibility of work-relatedness (see Paragraph 4.25). The existence of a sizable cluster of disease among workers employed in a particular area of the plant is a matter of fact. The possibility that this cluster is the product of chance is real, particularly because there is such a high incidence of breast cancer in the female population. This chance possibility is enhanced in turn by the absence of any robust evidence to suggest the presence of

a workplace carcinogen. However the possibility that the cancer is work-related is also real.

5.6 In this connection, the Panel has found it helpful to examine empirical data on clusters. While there are not much data, a report from Schulte et al. (1987) gives some information. They describe 61 clusters of cancer reported to NIOSH between 1978 and 1984. The cancers involved tended to be those of sites common to the general population. The index cases were retained in all their analyses. Only 16 of the clusters actually had an excess of observed over expected cancers. Of these 16, the excess was statistically significant in 8 clusters (at the 5% level). Among these 8, only one cluster satisfied the criteria of exposure and an appropriate latent period. Thus only 1 of the 61 would seriously raise the issue of compensability.

5.7 This result is material to the question of chance-relatedness. When a cluster arises through a chance deviation from the general population rate of cancer, the distribution of exposure deviations and of latent periods will also be determined by chance. A double coincidence is needed to produce a cluster which has credible exposure and latent periods. Therefore, elimination of clusters which do not satisfy exposure and latency requirements provides a second test for the cluster to pass. The first test is statistical significance which we know is not adequate because the index cases are included. The second test reduces the play of chance somewhat further. The results of the Schulte study, although not based on a large number of clusters, suggest that only 1.6% of clusters pass both the first and the second test.

5.8 In this light, it appears to some Panel Members that the possibility that the CGE cluster is chance-related would represent a relatively rare event. In weighing this possibility against work-relatedness, these Panel Members conclude that the balance is approximately even.

5.9 In the circumstances, and on a case by case basis, these Panel Members consider that the key considerations in awarding compensation should be each claimant's occupational history in the CWD department, and verification of a diagnosis of breast cancer or cancers of the body of the uterus or ovary. The generally recognized principle of workers' compensation that one takes the worker as one finds her should eliminate the relevance of such factors as a familial history of cancer and hormonal status. Given a diagnosis of breast, uterine or ovarian cancer, what is material is the duration of an individual's exposure to the CWD area and the latency period of the cancer. On a case-by-case basis, numerical criteria on these two counts should be approached flexibly lest, by being taken as hard and fast, they create delusions of precision.

As broad indicators and drawing upon the information in Table V of the Shannon study, these Panel Members suggest a minimum employment period among female workers in the CWD workplace of around 5 years and a minimum latency period of around 15 years.

5.10 In line with the above considerations, Panel Members Buck, Chong, LeVay and Stevens make the following finding:

FINDING 2: ON A CASE BY CASE BASIS, THE BOARD SHOULD ADJUDICATE CLAIMS FOR BREAST, UTERINE AND OVARIAN CANCERS ARISING FROM THE CWD AREA OF THE CGE DUFFERIN ST. PLANT IN THE CONTEXT OF SECTION 3(4) OF THE WORKERS' COMPENSATION ACT. EVIDENCE FOR AND AGAINST THE POSSIBILITY OF WORK-RELATEDNESS SHOULD BE TAKEN AS BALANCED WHEN THE CLAIMANT'S MINIMUM EMPLOYMENT PERIOD IN THE CWD AREA IS AROUND 5 YEARS AND THE LATENCY PERIOD IS AROUND 15 YEARS.

5.11 However, other Panel Members consider that the key considerations in awarding compensation should include, in addition to all of the above, continuing evidence of excess cancer at the hypothesized disease sites (breast alone or in combination with the ovary and body of uterus) among the CGE CWD female workers in Shannon's cohort. Such evidence could consist of 4 more cases of combined site cancers appearing during the 1983-87 followup period. The approximate SMbR for such a finding would be 219 which, tested using a one-sided test following Shannon's protocol, would yield a p value (or probability) of about 0.11 (or 11%). That is, the odds of finding 4 or more cases among these workers during this additional followup period (1983-87) by chance alone would be about 1 in 9. These Panel Members would regard the appearance of these additional cases in this time period as constituting a balancing of the evidence for and against the proposition of the work-relatedness of these cancers.

5.12 This line of reasoning leads Panel Members Dupré, Gibson and Miller to make the following finding:

FINDING 2A: ON A CASE BY CASE BASIS, THE BOARD SHOULD ADJUDICATE CLAIMS FOR BREAST, UTERINE AND OVARIAN CANCERS ARISING FROM THE CWD AREA OF THE CGE DUFFERIN ST. PLANT IN THE CONTEXT OF SECTION 3(4) OF THE WORKERS' COMPENSATION ACT. IN THOSE CASES WHERE THE CLAIMANT'S MINIMUM EMPLOYMENT PERIOD IN THE CWD AREA IS AROUND 5 YEARS AND THE LATENCY PERIOD IS AROUND 15 YEARS, EVIDENCE FOR AND AGAINST THE POSSIBILITY OF WORK-RELATEDNESS SHOULD BE TAKEN AS BALANCED ONCE THERE IS EVIDENCE OF CONTINUING EXCESS

DISEASE ARISING FROM THE CWD AREA OF THE CGE DUFFERIN ST. PLANT AMONG THESE WORKERS, SUCH AS 4 MORE CASES OF CANCER AT THE SITES OF INTEREST IDENTIFIED IN THE YEARS 1983 THROUGH 1987.

5.13 For their part, Panel Members Gagnon and Jolley reason as follows:

5.13a Since we do not know the actual causative agent and have no historical exposure data, eligibility rules requiring specific duration of exposure cannot be sustained.

While epidemiology is able to identify a probable connection between cancer of the breast, body of the uterus and ovary and the workplace, epidemiology cannot identify occupational disease in individual workers. Nor should compensation be limited only to those workers whose duration of exposure and latency periods fall within a statistical excess identified through epidemiological methods. This would ignore the contribution that the workplace made to each of the cancers of the breast, body of the uterus and ovary experienced in this group.

And eligibility rules continue to place the burden of proof on individual workers.

5.13b In line with the above considerations, Panel Members Gagnon and Jolley make the following finding:

FINDING 2B: THE BOARD SHOULD ENTER CANCER OF THE BREAST, BODY OF THE UTERUS AND OVARY INTO SCHEDULE 3 OF THE WORKERS' COMPENSATION ACT, AND THAT CANCER OF THE BREAST, BODY OF THE UTERUS AND OVARY BE DEEMED TO HAVE BEEN DUE TO THE NATURE OF WORK IN THE COILING AND WIRE DRAWING AREA OF THE CGE DUFFERIN STREET PLANT, UNLESS THE CONTRARY CAN BE PROVED.

6.0 CONCLUDING OBSERVATION

6.1 The present reference tellingly illustrates a matter that should be of growing concern among individual experts and public agencies involved with occupational health and workers' compensation. Dr. Philip Enterline of the University of Pittsburgh has eloquently captured the essence of this concern in a recent paper. To quote Dr. Enterline:

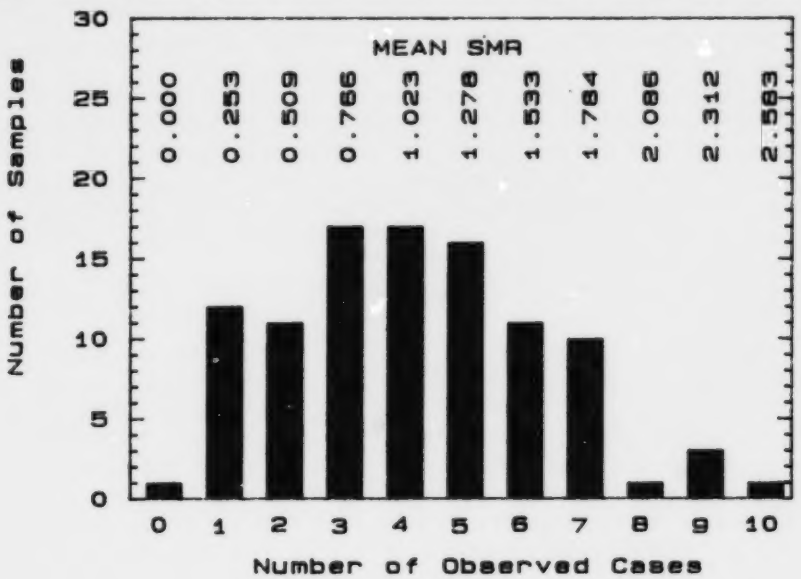
> "We have had considerable success in identifying cancer causing agents in the workplace using epidemiologic methods. This success had made us very sensitive to the occurrence of cancer clusters among workers in the belief

that identification of some common exposure could reveal the presence of a carcinogen and lead to preventive measures. This intense surveillance is both a blessing and a curse. On the one hand, it is a proven way of discovering environmental causes of cancer. On the other, it leads to false alarms or does not always lead to identification of a causal agent. It is easy to demonstrate, using tables of random number 5, how clusters can occur by chance and to demonstrate that when the number of comparisons made in identifying clusters is known there is a basis for their evaluation. Unfortunately, in most instances, when cancer clusters are detected in the workplace the number of comparisons made is unknown and the statistical significance of the cluster cannot be evaluated. Moreover, it is not usually recognized that in this situation when a study is made as a result of discovering a cluster in a particular population, the cases that make up the cluster cannot be included in a data set which tests the hypothesis that a cluster exists. This paper illustrates the above points by actual experiences." (Enterline, P.E.: Evaluating Cancer Clusters. Am. Ind. Hyg. Assn. J. 46: March, 1985, pp. B-10-13)

6.2 The particular situation covered by this Report has been complicated by the fact that the inclusion of index cases in the Shannon study of the CGE plant beclouded the issue of probable connection. The difficulty was further compounded by the non-existence of any comparable plant whose employee population could have been studied. The problem that arises in instances where a particular plant is unique is probably rare. But the possibility that a cluster is indeed a chance event is a matter of professional epidemiological concern that emphasizes the importance of approaching and reporting such studies with great respect for the apprehensions and expectations that they can arouse in worker populations.

FIGURE 1

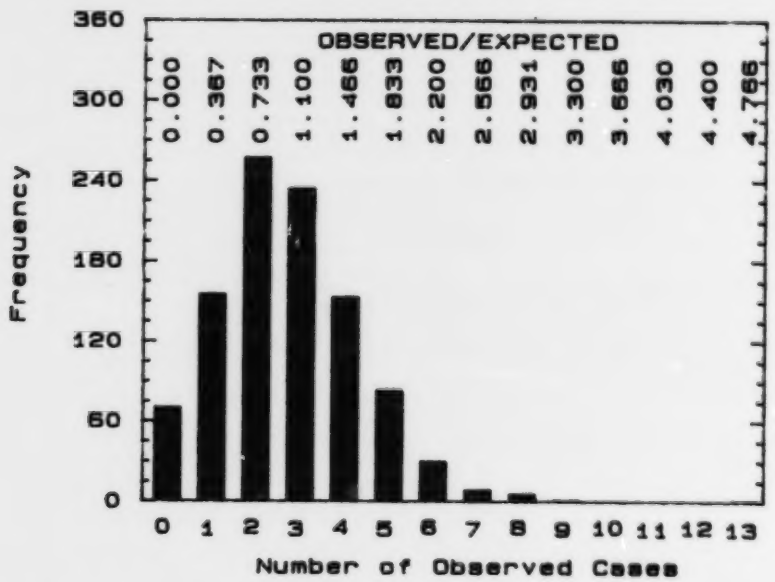
DISTRIBUTION OF STANDARDIZED MORTALITY RATIOS FOR BREAST CANCER FROM 100 SAMPLES FROM THE NATIONAL BREAST SCREENING STUDY



NOTES:
1. Expected numbers are based on the age, sex standardized rates for the entire NBSS cohort.
2. Each sample is a random draw of 6,178 members from the NBSS cohort.
3. For a given number of observed cases, sampling variation leads to variation in the expected number of cases.

FIGURE 2

DISTRIBUTION OF OBSERVED (AND OBSERVED TO EXPECTED) CASES IN 1,000 SAMPLES FROM THE NATIONAL BREAST SCREENING STUDY



NOTES: 1. Each sample is a random draw of 100 cohort members

2. Expected Number= Sample Size X Cohort Incidence
= 100 X 0.02727
= 2.727

APPENDIX A

LETTER OF REFERRAL

FROM THE

WORKERS' COMPENSATION BOARD

(DATED JUNE 24, 1987)

Workers' Compensation Board
Commission des accidents du travail

Elizabeth Kaegi, M.B.Ch.B., M.Sc.
Vice-President, Policy and Specialized Services

Elizabeth Kaegi, M.B.Ch.B., M.Sc.
Vice-présidente, Politique et services spéciaux

2 Bloor Street East
Toronto, Ontario
M4W 3C3

Telephone
416/927-6963

2, rue Bloor Est
Toronto, Ontario
M4W 3C3

Téléphone
(416) 927-6963

June 24, 1987.

Dr. J. M. Ham,
Chairman,
Industrial Disease Standards Panel,
Ontario Ministry of Labour,
10 King Street E., 7th Floor,
TORONTO, Ontario. M5C 1C3

Dear Doctor Ham:

Re: CGE Lamp Plant Study

In November, 1982 Mr. Elie Martel announced in the Legislature that 24 women working in the Coiling and Wire Drawing (CWD) Department of the Canadian General Electric Company lamp plant have been diagnosed as having tumors, a number of which were malignant and at least 5 women have died of cancer. As a result of these findings an epidemiological investigation was initiated in August 1983. The study was funded by the Workers' Compensation Board, the Ministry of Labour and the Canadian General Electric Company (CGE).

The final results of the epidemiological study were presented to the CGE workers on November 20, 1986 by the study investigator, Dr. Harry Shannon, Associate Professor of McMaster University. He concluded that there was a significant increase in breast cancer in women working in the CWD department of the CGE plant. Specifically, 8 cases of breast cancer were observed when only 4 were expected. At this meeting the researchers advised the workers to submit claims to the WCB for compensation. The study received media coverage in the Toronto Star on November 22, 1986. To date one claim has been received for compensation benefits.

...2

At the request of the Workers' Compensation Board, the study was reviewed by Dr. A. B. Miller of the University of Toronto. Dr. Miller submitted his report on January 14, 1987 and concluded, "I do not feel it is appropriate that the study be regarded as sufficient for compensation purposes at this time." Two Canadian General Electric consultants, Dr. Richard Monson and Dr. Otto Wong, have also reviewed drafts of the report. Both of these epidemiologists have raised serious concerns regarding the adequacy of this study.

Board staff have examined the original study, the comments of the various reviewers and the relevant scientific literature (copies of which are attached). They consider that the available evidence assessed in terms of the strength, consistency, temporality, and specificity of the association is currently insufficient to allow the development of a defensible and equitable policy with respect to breast or gynecological cancers for this occupational group.

The Board now requests the opinion of the Industrial Disease Standards Panel on this matter and would seek their specific advice in relation to the following questions:

1. In the Panel's opinion, is there an occupational association between working in the CGE Dufferin Street Lamp Plant Coiling and Wire Drawing Department, and

    (a) the development of breast cancer?
    (b) the development of gynecological cancers?

2. If it is determined that there is an occupational association between working in the Coiling and Wire Drawing Department of CGE and the development of cancer:

    (a) What is the Panel's opinion regarding the likely causal agent or process? In particular, is there any evidence to suggest that exposure to methylene chloride may cause an increased incidence of breast cancer and/or gynecological cancer in workers?

...3

(b) What should the standards of eligibility for compensation be? We considered the the following criteria:

- Duration and intensity of exposure.
- Latency period from time of first exposure.

(c) Under what circumstances would it be unlikely that there is an occupational cause? Should data be collected regarding such factors as:

- Familial history of breast or gynecological cancer.
- Hormonal status.
- Age at first pregnancy.
- Age of onset of cancer.

(d) Should the compensation approach be founded on the Statutory Schedule, Policy Guideline or on a case by case adjudication basis?

On behalf of the Board of Directors, I would like to thank you for considering this matter.

Yours truly,

Elizabeth Kaegi

/fm
enclosures

SUMMARY OF ATTACHMENTS

A copy of the study by Dr. Harry S. Shannon et al entitled "Cancer Morbidity in Lamp Manufacturing Workers", April, 1987.

Comments of Dr. A. B. Miller forwarded to Dr. Elizabeth Kaegi, WCB, on January 14, 1987.

Comments of Drs. R. Monson and O. Wong provided on behalf of Canadian General Electric.

Comments of Dr. N. B. Hilliard, Industrial Medicine Consultant, Policy and Program Development Department.

Various journal articles and letters of correspondence.

APPENDIX B

EVIDENTIARY CENTRE HOLDINGS

FOR

THE CCE LAMP PLANT ISSUE

APPENDIX B

EVIDENTIARY CENTRE HOLDINGS FOR THE CGE LAMP PLANT ISSUE

Andrews,D.F. CGE lamp plant study: a review of methodology. [Prepared for the IDSP]. January 4, 1988.

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Heller,J.; Martin,N.M. [Minutes of Meeting with Dr. Richman]. December 2, 1987.

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Threlfall,W.J.; Gallagher,M.A.; Spinelli,J.J.; Band,P.R. Reproductive variables as possible confounders in occupational studies of breast and ovarian cancer in females. Journal of occupational medicine. Vol.27,no.6(June 1985). p.448-450.

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Wong,O. A review of "Cancer Morbidity in Lamp Manufacturing Workers" (A Report by Shannon et al., dated September 5, 1986). November 4, 1986.

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